REMARKS

Claims 1-11 are pending in this case. Claims 1-4 are amended herein, all without prejudice and without acquiescence. Applicants reserve the right to pursue amended and cancelled subject matter in subsequent prosecution. Entry of the amendments and foregoing remarks are respectfully requested.

I. **Issue Under 35 USC §112, 2nd paragraph**.

Claims 2-4 are rejected under 35 USC §112, second paragraph as allegedly being indefinite.

Claims 2-4 have been amended to recite that wherein the placebo cushioning component is a bead or particle that the particle size can range from about 20μm up to about 500μm (claim 4) or from about 20 μm up to about 1000μm (claim 3) or from about 20 μm up to about 2000 μm (claim 2). It is thus now clear that when the cushioning component is a bead or particle it may have those recited size ranges. Withdrawal of the rejection is now respectfully requested.

II. **Issue Under 35 USC §102 (b)**.

Claims 1-11 are rejected under 35 USC §102(b) as allegedly being anticipated by Mount et al. Applicants disagree for the reasons stated below.

Mount discloses a generalized method for preparing a tablet from coated beads by including matrix cushioning agents. In particular, two cushioning agents (GPS) and (MCC) were interspersed with the drug beads which contained 10% theophylline. The pellet manufacturing step of Mount utilizes forced oven (40^0 C) drying (pages 612-613). There is no mention of any freeze drying in the Mount process. The oven drying process of Mount and the freeze drying process of the instant invention clearly yield dosage forms with different properties, albeit cushioning matrices are included in both cases.

As evident from the disclosure of the invention, the freeze drying of the admixture of the placebo cushioning component and the active-loaded particles creates a cushioning component with a uniform distribution of active components throughout the cushioning component and yields a very porous layer of cushioning component that surrounds the active-loaded particles (page 16, paragraph [0085]). Moreover, the freeze-drying process of the admixture creates a non-hygroscopic active cushioning component and the coatings of the active loaded particles which can withstand a compression force during tabletting of as high as 1000kg thus producing a non-hygroscopic cushioning component that does not require any special handling or packaging (page 16, paragraph [0085]). In contrast, the method of Mount produces tablets which do not manifest the same desirable physical attributes as the instant invention. The specification of the instant application makes mention of the shortcomings of Habib and Mount (at page 2). Additionally, Mount makes no disclosure that the tablets prepared according to his method (using oven drying)would in fact yield tablets which have the same hygroscopic properties or could in fact withstand compression forces in the tabletting process as high as 1000kg or more (see

Figures 3,4 and 5 of Mount). The freeze drying step of the pending claims produces a composition which is not the same as the composition produced by the oven drying process of Mount and thus Mount fails to teach the elements of the present invention and thus should not be considered an anticipatory reference.

Similarly, Botzolakis should not be considered anticipatory to claims 1-11 either. Botzolakis discloses an admixture of a drug with silicon dioxide, microcrystalline cellulose and crospovidone, where the admixture is dried in an oven, milled and tabletted. The combination disclosed in Botzolakis is not freeze-dried, but oven dried. For similar reasons discussed above with regard to the Mount reference, the oven drying step of Botzolakis does not produce the same results and thus yield the same compressible dosage forms with the same physical characteristics as the present invention and consequently Botzolakis fails to teach an essential element of the present invention. Therefore, Bozolakis should not be considered an anticipatory reference.

III. **Issue Under 35 USC §103**.

Claims 1-11 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Botzolakis in view of Habib. Applicants respectfully disagree for the reasons articulated below.

Botzolakis fails to teach or suggest at least one element of claim 1- the freeze drying of the admixture of a placebo cushioning component and active-loaded particles to form the active cushioning component. Habib does not remedy this deficiency in Botzolakis. Habib teaches freeze-drying of the cushioning component alone prior to combining it with the biologically active ingredient loaded beads (see col. 65, lines 18-21). Habib does not teach or suggest freeze-drying of the admixture of the cushioning component and biologically active ingredient-loaded beads to form the active cushioning component as required by the claims of the instant invention. Nowhere does Habib teach or suggest freeze-drying of the active-loaded particles alone or together with the placebo cushioning component. In fact, Habib asserts that "the means for preparing the biologically active ingredient-loaded beads is not critical" for the invention (col. 30, lines 39-41). Thus, the combination of Botzolakis and Habib fails to teach or suggest at least one element of the claimed invention. Moreover, the combination of Botzolakis and Habib does not yield compressible dosage forms which have the desired properties of the dosage forms produced by freeze drying of the present invention.

As described in the present specification and recited in amended claim 1, the freeze-drying of the admixture forms an active cushioning component with a uniform distribution of active components throughout the cushioning component and produces a very porous layer of cushioning that surrounds the active-loaded particles which allows for coatings of the active-loaded particles to withstand compression forces as high as 1000kg or more during tabletting. The freeze-drying step of the present claims produces a composition with unexpected characteristics and is non-obvious in view of Botzolakis and Habib, alone or in combination. Clearly, Botzolakis and Habib fail to yield such a composition.

Claims 1-11 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Habib in view of Botzolakis. Applicants respectfully disagree for the reasons articulated below.

Habib does not teach or suggest combining the placebo cushioning component with the active-loaded particles prior to freeze drying AND Habib fails to teach or suggest freeze-drying of the admixture of the placebo cushioning component and the active-loaded particles to form the active cushioning component of the claimed invention.

Botzolakis fails to remedy the deficiencies of Habib. Botzolakis like Kabib fails to teach or suggest freeze-drying of the admixture of the placebo cushioning component and the active-loaded particles to from the active cushioning component which has a uniform distribution of active components throughout the cushioning component and is characterized by an active cushioning component with certain desired physical properties, as recited in claim 1.

Therefore, for at least the foregoing reasons, Applicants assert that claims 1-11 are not obvious over Botzolakis in view of Habib or Habib in view of Botzolakis and respectfully request that this rejection be withdrawn.

IV. **Double Patenting Rejection**.

Claims 1-11 remain rejected on the ground of obviousness-type double patenting as being unpatentable over claims 16-30 of US Patent 5,780,055 in view of US Patent 4,910,023 to Botzolakis. Applicants respectfully disagree.

Claims 1-11 specify that the admixture of the placebo cushioning component and active-loaded particles is frees-dried to from the active cushioning component. Claims 16-30 of Habib are directed to a tablet comprising a biologically active ingredient-loaded beads and cushioning beads, wherein only the cushioning beads were prepared by freeze-drying prior to combining them with active ingredient-loaded beads (col. 87, lines 58-64). Claims 16-30 of Habib do not specify the freeze-drying of the admixture of the placebo cushioning component and the active-loaded particles and thus fails to teach or suggest preparation of the active cushioning component of the claims of the present invention. Claim 16 of Habib is directed to cushioning beads comprising microcrystalline cellulose which are prepared by extrusion-spheronization followed by freeze-drying. Also,as articulated above, oven drying is distinct from freeze drying and clearly yields compositions with different physical characteristics. Both Habib and Botzolakis fail to teach or suggest that freeze-drying of the admixture of the placebo cushioning component and the active loaded particles can yield dosage forms with desirable physical characteristics (as recited in claim 1 of the present invention). In view of these points, Applicants believe that claims 1-11 are patentably distinct from claims 16-30 of Habib in view of the Botzolakis patent. Therefore, Applicants respectfully request that this rejection be withdrawn.

V. **Conclusion**:

Since all claim rejections are believed to be overcome, all claims are now believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with the Applicants' position then a telephonic interview is respectfully requested to discuss any remaining issues and thus expedite the eventual allowance of the application.

Applicants believe that no fee is due with this submission other than the fee for the RCE and the extension of time request for replying to this Office Action. However, if a fee is due, please charge our Deposit Account No. 21-0684 .

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